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REMARKS

Pending Claims and Support for Amendments

After entry of the amendment, Claims 1-2 and 4-9 are pending. The claims have been amended to correct formal matters only. No new matter has been added.

Based on the following remarks, Applicant respectfully requests reconsideration and allowance of the pending claims.

Restriction Requirement

The Examiner has required restriction to a single disclosed species for prosecution on the merits.

Applicant elects the invention of Claims 1-9, with traverse.

Applicant respectfully submits that the restriction requirement is erroneous and should be withdrawn. The Examiner supports the restriction requirement by alleging that the claims are directed to patentably distinct species of the claimed invention: the species of neoplasm, specifically, solid tumors and blood borne tumors. However, according to MPEP § 803 the Examiner must examine an entire application on the merits, including claims to distinct or independent inventions, so long as the search and examination of the entire applications can be made without serious burden. Applicant respectfully submits that examination of the claims of the entire application will not impose an undue burden.

37 C.F.R. 1.141 provides that a reasonable number of species may be claimed in one application if the application includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form or otherwise include all the limitations of the generic claim. See MPEP 806.04(a). Applicant submits that generic Claim 1 is currently allowable and all species claims are written in dependent form. Thus, no restriction is necessary.

Applicant respectfully requests that the Examiner withdraw the restriction requirement.

Defective Oath/Declaration

The Examiner stated that the oath or declaration is defective because the claim for benefit from the provisional application contains an invalid application number.

Applicant, concurrent with this response, has submitted a new declaration in compliance with 37 C.F.R. § 1.67(a).

Claim Objections

Claim 2 was objected to because it lacked a period at the end of the claim. Applicant has amended Claim 2 to correct this informality.

Indefiniteness Rejection

At page 4 of the Office Action, the Examiner rejected Claim 3 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant has canceled Claim 3.

Obviousness Rejection

At page 4 of the Office Action, the Examiner rejected Claims 1-2 under 35 U.S.C. § 103(a) as being unpatentable over Watkins, Jr. *et al.* (*Int. J. Cancer*: 14, 79-807 (1974)) and U.S. Patent No. 3,792, 159 to Green *et al.* Applicant respectfully traverses this rejection and requests reconsideration and withdrawal thereof.

Watkins *et al.* teaches solid tumors cells treated with neuraminidase *in vitro* then cultured in the presence of host blood lymphocytes. Watkins *et al.* also describes that these cells may be reinjected into mice. Watkins *et al.* only teaches the administration of neuraminidase to individual tumor cells outside the body. The claims as drafted recite a method and composition that is administered systemically to a patient to treat a neoplasm.

Watkins *et al.* describes *in vitro* manipulation of murine neoplastic cells. Watkins *et al.* does not teach that administration of a very small amount of neuraminidase or a fragment of neuraminidase systemically to a patient with a neoplasm. In the present invention, as now claimed, the neuraminidase is not administered directly to the tumor cells outside the body. In fact, the present invention, as claimed, does not treat tumor cells directly with neuraminidase. It is respectfully submitted that the invention as recited in the claims achieves results with significant advantages that are not suggested in the Watkins *et al.* reference. The claimed invention teaches a method whereby a very dilute solution (small amount) of

neuraminidase is administered systemically to a patient with a neoplasm that is at a remote site from the site of administration of the neuraminidase. According to the claimed invention, it is not necessary nor advisable to directly treat the neoplastic cells outside the body with neuraminidase. Thus, because the present invention, as claimed, teaches a method and composition comprising administering an effective amount of neuraminidase systemically to a patient with a neoplasm at a site remote from the administration site, it would not be obvious to practice the claimed invention after reading Watkins *et al.* because Watkins *et al.* teaches directly treating neoplastic cells outside the body with neuraminidase. This is a completely different process from the claimed invention.

Green *et al.* teaches a micro-fine precipitate of tyrosine containing an allergen. This is removed from solution by centrifugation or filtration, wash and resuspended in a liquid physiologically-acceptable carrier such as phenol saline, to produce an injectable composition suitable for use in desensitization therapy.

It is respectfully submitted that it would not have been obvious to one skilled in the art to modify Green *et al.* for treatment of tumors. Green *et al.* is clearly nonanalogous. It is not in the field of the applicant's endeavor, nor is it reasonably pertinent to the particular problem with which the inventor was concerned. See MPEP 2145. Green *et al.* describes a process for allergen desensitization therapy. One with skill in the art would not have been motivated to use such a therapy for treating tumors. Green *et al.* is also not pertinent to problem of cancer. Finally, it would not have been obvious to modify Watkins *et al.* in light of Green *et al.* to achieve to the claimed invention and the rejection should be withdrawn.

MARKED COPY OF AMENDMENTS

Amendments in the Claims

In accordance with 37 C.F.R. § 1.121(c), the following version of the claims as rewritten by the foregoing amendment shows all the changes made relative to the previous version of the claim.

2. (Amended) The method of Claim 1, wherein the neuraminidase is dissolved in a phenol-saline solution.

Claim 3 has been canceled.



CONCLUSION

The foregoing is submitted as a full and complete response to the Office Action mailed October 10, 2001. Applicants respectfully submit that the present application is in condition for immediate allowance. An early notification is earnestly solicited. If the Examiner has any questions, or further issues remain to be resolved, the Examiner is requested to contact the undersigned at 404.745.2415 prior to the issuance of any final office action.

Respectfully submitted,

A handwritten signature of Theodore M. Green in cursive script.

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